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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/491,500	01/26/00	BLACK K	CEDAR043-453

EXAMINER	
SORBELLO,E	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application r proceeding.

Commissioner of Patents and Trademarks

Interview Summary	Application No. 09/491,500	Applicant(s) BLACK ET AL.	
	Examiner Eleanor Sorbello	Art Unit 1633	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Eleanor Sorbello*.

(2) *Deborah Clark*.

(3) *Nissan Steinberg*.

(4) *Dr. K. Black and (5) Dr. Nagendra S. Ningaraj*.

Date of Interview: *14 March 2001* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description:

Claim(s) discussed: *1-34 and 97-109* .

Identification of prior art discussed: *Black et al. (US Patent NO: 5,434,137) and Sobey et al. in view of Cherksey.* .

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:
The above 5 persons mentioned above were in attendance at the telephone interview. Mr. Steinberg set out to clarify that which they thought was not clear from their Responses to both the First and Second Office Actions. He mentioned that of the 4 groups of potassium channels, inverse rectifier channel, (KIR), potassium voltage channel, (Kv), potassium ATP and potassium Ca++channel (K-Ca++), the instant invention deals with the last two types, namely K-ATP channel (K-ATP) and K-Ca++. Applicants intend amending the claims 1, 97, 108 to include the following phrase "of a Calcium-activated or ATP-sensitive K-channel agonist, said agonist being" after the phrase potassium channel agonist, and before the phrase "other than bradykinin". Applicants amendments are intended to clarify the subject matter claimed.

Mr. Steinberg stated that the rejection under 35 USC 103 was not obvious as Sobey did not use other compounds for this purpose, and Sobey did not show that the compounds he used increased vasodilation which increased permeability. Dr. Black stated that at the time of filing of the patent 947, the mechanism of increased blood to the brain was not clear. Dr. Black stated that vasodilation and permeability were not obvious and were dependent one from the other, but in the instant application the claim to increased permeability was unique to the brain capillaries and due to the activation of 2 potassium channels namely K-ATP and K-Ca++, ie. ATP dependent and Ca++ dependent channels. Dr. Black also pointed out later in the interview that the main difference and point that was not noticed in two office actions and responses, regarding the Sobey reference was that, Sobey teaches that K-Ca++ channels will cause normal (and not select only the abnormal blood vessels to dilate, as in the instant case) blood vessels to increase dilation and therefore increase permeability. He reiterated that applicants did not find increased blood capillaries in the entire brain, but only in the abnormal brain tissue. Dr. Black stated that all the cited references failed to teach the relative quantities of K-Ca++ channels in abnormal versus normal tissue, wherein that in abnormal brain tissues had a much higher number of K-Ca++ channels, after the administration of the agonists, which excluded bradykinin.

Mr. Steinberg, pointed examiner to support in the specification regarding the chemical differences between the K-Ca++ channel agonists of the instant invention and that of bradykinin or its analogs(which are short peptides), and that bradykinin and its analogs were chemically distinct.

Mr. Steinberg referred to claims 108 and 109, directed to kits, and stated that he did not agree with the rejection made by the examiner as being obvious. SPE-Clark stated that claims were rejected due to the breadth encompassed by the claims. SPE-Clark also stated that those claims could possibly be made into Jepsom type claims.

Mr. Steinberg next referred to the 35 USC 112/first rejection rejecting claims 1-34 and 97-109 and does not agree with the examiner's rejection as in 2nd office action, item 15, wherein examiner rejects the claims based on non-enablement, and cites the reference by Sabate et al., used in the rejection, wherein Sabate teaches that the blood brain barrier prevents access to the brain of numerous macromolecules. Mr. Steinberg stated that applicants have provided numerous macromolecules in the specification that were being used at the time the application was filed for crossing the blood brain barrier, and did not agree with the non-enablement issue. Mr. Steinberg stated that the specification on page 13, lists the macromolecules that are being currently used for crossing the blood brain barrier.

SPE-Clark added that additionally the claims 6 and 23 are problematic in that they are not enabled as a method of selectively delivering a medicant wherein the medicant is any expression vector, any viral vector, any protein, any oligonucleotide, any nucleotide analog, unless the state of the art at the time of filing supported the aforementioned claims, and the experimentation was known to one skilled in the art as routine.

Mr. Steinberg next referred to the double patenting rejection, and SPE-Clark stated that it may fall due to the amendment of the claims which therefore may remove the 103(a) rejection.

SPE-Clark requested applicants to file a response with the amendments, which will include the points which were clarified, and others that required more detailed explanations, so examiner Sorbello will be in a better position to consider all the points not hitherto considered.

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